

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>NMRPCT001</b>	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. <b>PCT/GB2004/005160</b>	International filing date ( <i>day/month/year</i> ) <b>09 December 2004 (09.12.2004)</b>	Priority date ( <i>day/month/year</i> ) <b>30 December 2003 (30.12.2003)</b>
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant <b>ADPHIL LIMITED</b>		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report <b>03 July 2006 (03.07.2006)</b>
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Nora Lindner</div> e-mail: pt02@wipo.int

# PATENT COOPERATION TREATY

REC'D 15 APR 2005

WIPO

PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2004/005160

International filing date (day/month/year)  
09.12.2004

Priority date (day/month/year)  
30.12.2003

International Patent Classification (IPC) or both national classification and IPC  
G01M3/22

Applicant  
ADPHIL LIMITED

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for International preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2004/005160

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2004/005160

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	6,7,9,10,13,15-17,19-22,25,27-30,32-35,37-39
	No: Claims	1,2,3,4,5,8,11,12,14,18,23,24,26,31,36
Inventive step (IS)	Yes: Claims	15-17
	No: Claims	1-14,18-39
Industrial applicability (IA)	Yes: Claims	1-39
	No: Claims	

2. Citations and explanations

**see separate sheet**

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**Box No. VIII Certain observations on the International application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1 Reference is made to the following documents:**

- D1: US-B1-6 626 027 (DAVEY) 30 September 2003 (2003-09-30)
- D2: US-A-4 636 475 (PRICE ET AL) 13 January 1987 (1987-01-13)
- D3: GB-A-2 376 748 (STEPHEN DANIEL HOATH) 24 December 2002 (2002-12-24)
- D4: GB-A-2 376 749 (STEPHEN DANIEL HOATH) 24 December 2002 (2002-12-24)
- D5: US-B1-6 346 668 (MCGREW) 12 February 2002 (2002-02-12)
- D6: US-A-4 665 364 (HANAWA) 12 May 1987 (1987-05-12)

**2 INDEPENDENT CLAIMS 1-4**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document) a method of testing the integrity of a barrier (abstract) by transferring material from one side of the barrier through a continuous path directly into a NMR analysis system (column 6, lines 7-13; figure 1) and using the NMR analysis system to determine from the transferred material if there has been any leakage through the barrier (abstract).
- 2.2 The independent method claims 2 and 3 are also considered not new, because their subject-matter is disclosed in document D1 (abstract; figure 3; column 4, line 35; column 6, lines 7-13).
- 2.3 The independent method claim 4 is also considered not new, because its subject-matter is disclosed in document D2 (abstract; column 9, lines 37-48).

**3 INDEPENDENT CLAIM 24 and 36**

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 24 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document) a test equipment having means suitable for validating inhaler integrity using a NMR analysis system for analysis of material leakage accumulated within the NMR analysis system (abstract; figures 1 and 2).
- 3.2 The independent product claim 36 is also considered not new, because its subject-matter is disclosed in document D1.

**4 DEPENDENT CLAIMS 2-5, 7-14, 18-23, 25-27, 29-35, 37-39**

Dependent claims 2-5, 7-14, 18-23, 25-27, 29-35, 37-39 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see documents D1-D6 and the corresponding passages cited in the search report.

**5 DEPENDENT CLAIMS 15, 16, 17 and 28**

Claims 15, 16, 17 and 28 concern method steps describing different ways of transferring the accumulated leaked material to the NMR analysis system. These steps are not disclosed in the prior art and are therefore new. The transferring of said material between an independent accumulation chamber containing the tested container and a fixed NMR analysis system is efficient for a production line where many containers have to be tested on-going.

**Re Item VIII**

**Certain observations on the international application**

- 6.1 Although claims 1-4 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
- 6.2 The term "directly" used in claim 1 is vague and unclear and leave the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.
- 6.3 None of the claims are drafted in a two-part form, contrary to the requirements of Rule 6.3(b) PCT.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB2004/005160

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01M3/22

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 626 027 B1 (DAVEY) 30 September 2003 (2003-09-30) cited in the application	1-3, 5, 6, 8-14, 19-27, 29-39
Y	abstract column 1, line 7 - line 14 column 1, line 39 column 1, line 53 column 2, line 35 - line 50 column 3, line 6 - line 19 column 4, line 23 - line 24 column 4, line 47 - line 60 column 6, line 7 - line 13 figures 1,3 column 4, line 35 ----- -/--	7

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

12 April 2005

Date of mailing of the international search report

19/04/2005

Name and mailing address of the ISA

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB2004/005160

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 636 475 A (PRICE ET AL) 13 January 1987 (1987-01-13) abstract column 9, line 9 - line 48 figure 21 -----	1-5,8,18
Y	GB 2 376 748 A (STEPHEN DANIEL HOATH) 24 December 2002 (2002-12-24) cited in the application	7
A	abstract page 1, paragraphs 1,2,6 page 2, paragraph 5 figures 1,2 page 3, paragraph 1 -----	6,13,29
A	GB 2 376 749 A (STEPHEN DANIEL HOATH) 24 December 2002 (2002-12-24) cited in the application abstract page 1, paragraph 6 page 2, paragraph 1 page 3, paragraphs 3,8 -----	7,34
A	US 6 346 668 B1 (MCGREW) 12 February 2002 (2002-02-12) abstract figures 8,9 -----	19-22, 30,32
A	US 4 665 364 A (HANAWA) 12 May 1987 (1987-05-12) abstract -----	33

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/005160

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6626027	B1	30-09-2003	NONE	
US 4636475	A	13-01-1987	US 4521372 A BE 894173 A1 CA 1195785 A1 CA 1212248 A2 CH 652097 A5 DE 3231250 A1 ES 8502287 A1 FR 2515346 A1 GB 2104713 A ,B IT 1155920 B JP 58042945 A SE 449806 B SE 8204852 A	04-06-1985 16-12-1982 22-10-1985 07-10-1986 31-10-1985 17-03-1983 16-03-1985 29-04-1983 09-03-1983 28-01-1987 12-03-1983 18-05-1987 25-08-1982
GB 2376748	A	24-12-2002	NONE	
GB 2376749	A	24-12-2002	NONE	
US 6346668	B1	12-02-2002	NONE	
US 4665364	A	12-05-1987	JP 1861702 C JP 5077419 B JP 60165951 A DE 3569614 D1 EP 0152069 A2	08-08-1994 26-10-1993 29-08-1985 24-05-1989 21-08-1985